DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740

NOV 18 2005

Egil Nilsen
Business Development Manager
Natural ASA
Industriveien 42
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Norway

Dear Mr. Nilsen:

This is to inform you that the notification, dated September 1, 2005 that you submitted pursuant to 21 U.S.C. 350b(a)(2)(section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)) was filed by the Food and Drug Administration (FDA) on September 6, 2005. Your notification concerns the substance that you call "Omega-3 Phospholipids" that you identify as a new dietary ingredient and intend to market as a dietary supplement product.

According to your notification, the recommended use of softgel capsules containing the substance that you call "Omega-3 Phospholipids" will be "the consumption of 3 g or 1 capsule 3 times daily with meals." Your notification also states that your ingredient "may also be used in other applications such as nutritional bars and liquid formulations, which would provide the same daily dose as the capsule formulation."

Under 21 U.S.C. 350b(a), the manufacturer or distributor of a dietary supplement containing a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered must submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under 21 U.S.C. 350b (a) (2), there must be a history of use or other evidence of safety establishing that the new dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is considered to be adulterated under 21 U.S.C. 342(f) (1) (B) (section 402(f)(1)(B) of the Act) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

FDA has carefully considered the information in your submission and the agency has concerns about the evidence on which you rely to support your conclusion that "Omega-3 Phospholipids" will reasonably be expected to be safe.

FDA has carefully considered the information in your submission and the agency has concerns about the evidence on which you rely to support your conclusion that "Omega-3 Phospholipids" will reasonably be expected to be safe.

Your notification states that the substance that you call "Omega-3 Phospholipids" "may also be used in other applications such as nutritional bars and liquid formulations". It is unclear to FDA whether your "nutritional bars and liquid formulations" will be marketed as dietary supplement products or as conventional foods.

FDA was unable to determine the identity of the substance that you call "Omega-3 Phospholipids". According to your notification, your ingredient is manufactured from vegetable phospholipids, concentrated fish oil ethyl ester, a lipozyme immobilized enzyme, and a food-grade triglyceride carrier. The resulting product contains inter-esterified material and a variety of fats and oils including omega-3 phospholipids, docosahexanoic acid (DHA) and eicosapentanoic acid (EPA). Based on the descriptions of the manufacturing process and analyses of the product contained in the notification, the identity of the substance that you call "Omega-3 Phospholipids" is unclear to FDA. For example, the source of the concentrated fish oil and the identity of the triglyceride carrier (marine or vegetable) used to produce your ingredient are not described. Furthermore, the products of the various inter-esterification reactions are not identified or described.

In addition, while your notification contains some information about the safety of DHA and EPA, the notification does not address the safety of the other components of your ingredient. Furthermore, the notification does not present history of use or other evidence of safety for any material that is identical or similar to the substance that you call "Omega-3 Phospholipids". Because the identity of the substance that you call "Omega-3 Phospholipids" is unclear, it is unclear how your ingredient is qualitatively or quantitatively similar to the substances described in the safety information you relied on in your notification or how that information is relevant to evaluating the safe use of the substance that you call "Omega-3 Phospholipids".

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that the substance that you call "Omega-3 Phospholipids", when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe. Therefore, your product may be adulterated under 21 U.S.C. 342(f)(1)(B) as a dietary supplement that contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such a product into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

Your notification will be kept confidential for 90 days after the filing date of September 6, 2005. After the 90-day date, the notification will be placed on public display at FDA's Docket Management Branch in docket number 95S-0316. Prior to that date, you may wish to identify in writing specifically what information you believe is proprietary, trade secret or otherwise confidential for FDA's consideration.

If you have any questions concerning this matter please contact Dr. Linda Pellicore at (301) 436-2375.

Sincerely yours,

Linda S Pellicore

for Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety and Applied Nutrition